

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 561 Human Papillomavirus  
**SPONSOR(S):** Homan and others  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 660

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| REFERENCE                                | ACTION                  | ANALYST       | STAFF DIRECTOR |
|--|-------------------------|---------------|----------------|
| 1) <u>Committee on K-12</u>              | <u></u>                 | <u>Ahearn</u> | <u>Ahearn</u>  |
| 2) <u>Schools &amp; Learning Council</u> | <u>13 Y, 0 N, As CS</u> | <u>Ahearn</u> | <u>Cobb</u>    |
| 3) <u>Policy &amp; Budget Council</u>    | <u></u>                 | <u></u>       | <u></u>        |
| 4) <u></u>                               | <u></u>                 | <u></u>       | <u></u>        |
| 5) <u></u>                               | <u></u>                 | <u></u>       | <u></u>        |

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### SUMMARY ANALYSIS

The human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. By age 50, at least 80 percent of women will have acquired the HPV infection at some point in their lives. The HPV vaccine was released in June for use in females age 9-26. The Advisory Committee on Immunization Practices recommended the vaccine for 11 to 12 year old females. GARDASIL™ (a vaccine produced by Merck & Co., Inc.) protects against 4 of the most common strains of HPV.

The bill requires that by no later than January 1, 2008, the Department of Health adopt a rule adding the HPV to the list of communicable diseases for which immunizations are recommended.

The bill further provides that, beginning with the 2008-2009 school year, the parent or guardian of each student entering grade 6 for whom the HPV vaccine is approved by the United States Food and Drug Administration, must be provided information by the school concerning the connection between the HPV and cervical cancer and that a vaccine which helps prevent HPV infection is available and recommended to be given to females before they enter grade 8.

Finally, the bill provides that the information given the parents or guardians be developed by the Department of Health.

The bill does not appear to have a fiscal impact on state or local governments; however, the school districts will experience some expense associated with disseminating information to the parents.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES ANALYSIS:

This bill does not appear to implicate any of the principles.

#### B. EFFECT OF PROPOSED CHANGES:

##### Cervical Cancer

Cancer of the cervix is the second most common type of cancer among women worldwide. About 80 percent of cervical cancer cases occur in developing countries.<sup>1</sup> In 2005, the American Cancer Society estimated that approximately 490,000 new cases would be diagnosed worldwide that year. In the United States, cervical cancer is the 14<sup>th</sup> most common type of cancer in women.<sup>2</sup> An estimated 11,150 cases of invasive cervical cancer are expected to be diagnosed in the United States in 2007. Of those, 850 cases of new cervical cancer are estimated to occur in Florida in 2007.<sup>3</sup> Cervical Cancer incidence rates have decreased approximately 75 percent and death rates have decreased approximately 70 percent since the 1950s, largely because of screening with the Papanicolaou (Pap) test.<sup>4</sup> Cervical cancer is one of the most successfully treated cancers with a 5-year survival rate of 92 percent for localized cancers.<sup>5</sup>

##### Human Papillomavirus (HPV)

Genital human papillomavirus is the most common sexually transmitted infection in the United States.<sup>6</sup> An estimated 6.2 million persons are newly infected every year. The majority of infections are transient and asymptomatic with 70 percent of new infections clearing within one year and 90 percent clearing within 2 years. The median duration of a new infection is 8 months.<sup>7</sup> Of approximately 100 HPV types, over 40 types affect the genital area. Approximately 70 percent of cervical cancers worldwide are caused by HPV types 16 and 18. While infection with high risk types of HPV is considered necessary for the development of cervical cancer, the majority of women with high-risk HPV infection do not develop cancer.<sup>8</sup>

##### The Licensed HPV Vaccine

The U.S. Food and Drug Administration licensed a quadrivalent HPV vaccine on June 8, 2006, which has been shown in clinical trials to have high efficacy in preventing persistent HPV infection, cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions and genital warts caused by HPV types 6, 11, 16, and 18 among females who had not already been infected with the respective HPV type. The vaccine is administered by an intramuscular injection in three doses administered over a six-month period. The recommended age for vaccination of females is 11-12 years. The vaccine can be administered to females as young as age 9 and as old as age 26. The vaccine is produced by Merck & Co., Inc. and is marketed under the name GARDASIL™.

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<sup>1</sup> American Cancer Society, *Cancer Facts and Figures 2005* p. 27

<sup>2</sup> *Id.*

<sup>3</sup> American Cancer Society, *Cancer Facts and Figures 2007* p. 20.

<sup>4</sup> Centers for Disease Control and Prevention, "Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*. Vol. 56 (Early Release). March 12, 2007.

<sup>5</sup> American Cancer Society, *Cancer Facts and Figures 2007* p. 21.

<sup>6</sup> Centers for Disease Control and Prevention, "Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*. Vol. 56 (Early Release) March 12, 2007.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

## School Immunizations

Section 1003.22(4), F.S., requires immunizations for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by rules of the DOH, as a condition for entry into school. The statute provides two reasons for exemption from this requirement: If the parent objects in writing stating that the immunizations conflict with his or her religious beliefs or if a licensed physician certifies in writing that the child should be exempt from the required immunization for medical reasons.

Neither s. 1003.22(3), F.S., nor Department of Health rules, require immunization for the HPV. However, the DOH "routinely informs the parents or guardians of female patients in the age range of 11-12 years of age who present for services at county health department that the HPV vaccine is available [at no cost] for those who are eligible under the federal Vaccines for Children Program (VFC). Children age 0-18 are eligible for the VPC Program if they meet one of the following criteria: Medicaid covered, uninsured, underinsured (insurance does not cover immunization), Alaskan Native or American Indian."<sup>9</sup>

## Proposed Changes

The bill requires that by no later than January 1, 2008, the Department of Health adopt a rule adding the HPV to the list of communicable diseases for which immunizations are recommended.

The bill further provides that, beginning with the 2008-2009 school year, the parent or guardian of each student entering grade 6 for whom the HPV vaccine is approved by the United States Food and Drug Administration, must be provided information by the school concerning the connection between the HPV and cervical cancer and that a vaccine which helps prevent HPV infection is available and recommended to be given to females before they enter grade 8.

Finally, the bill provides that the information given the parents or guardians be developed by the Department of Health.

### C. SECTION DIRECTORY:

Section 1. Creates an unnumbered section of law regarding dissemination of HPV information.

Section 2. Provides an effective date of July 1, 2007.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

This bill does not appear to have a fiscal impact on state government revenues.

#### 2. Expenditures:

This bill does not appear to have a fiscal impact on state government expenditures.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

#### 1. Revenues:

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<sup>9</sup> DOH analysis, HB 561, Feb. 13, 2007.  
STORAGE NAME: h0561c.SLC.doc  
DATE: 4/11/2007

This bill does not appear to have a fiscal impact on local government revenues.

2. Expenditures:

This bill does not appear to be a fiscal impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This bill does not appear to have a direct economic impact on the private sector.

D. FISCAL COMMENTS:

There will be some costs to the school districts associated with the dissemination of information regarding HPV. These costs are indeterminate but should not be substantial.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to apply to counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill requires that by no later than January 1, 2008, the Department of Health adopt a rule adding the HPV to the list of communicable diseases for which immunizations are recommended.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

### IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On April 4, 2007, the Schools and Learning Council adopted one amendment by Representatives Pickens and Traviesa that eliminated the requirement that certain students are to receive the HPV vaccine in order for those students to be admitted to school, and substituted the requirement that beginning with the 2008-2009 school year, the parent or guardian of each student entering grade 6 for whom the HPV vaccine is approved by the United States Food and Drug Administration, must be provided information by the school concerning the connection between the HPV and cervical cancer and that a vaccine which helps prevent HPV infection is available and recommended to be given to females before they enter grade 8. The amendment requires the Department of Health to develop the information to be given to the parents; whereas, the bill required the Department of Education, in consultation with the Department of Health, to develop the information. The bill, as amended, was reported favorably by the council as a committee substitute.